

## MODELLING OF MANAGEMENT SYSTEM OF ENVIRONMENTAL TOXICOLOGY RESEARCH LABORATORY

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### **Abstract**

The environmental loads have serious burden both in individual and in social levels. The endocrine disruptor compounds (EDC) may cause endometriosis, fibrosis, childhood obesity, adulthood diabetes (type II.), cryptorchidism, male infertility and diminution of the levels of testosterone. Within the EU, this is approximately € 163 billion worth of specific health expenditure annually. Currently there is no standard method to examine these agents, in the environmental toxicology (Et). This issue is examined with several proceedings by environmental toxicology research laboratories (EtRL), however there are difficulties to compare the results of the laboratories. To solve this problem, the aim of this paper is to demonstrate a virtual verification method, using a solution, in which the operation of research unit is matched in the international requirement system. With the aim of providing comparable and reliable data from EtRL research and/or project results. At the same time, the safe handling of this data system is examined using the knowledge of the network studies, and this information is handled with virtual verification in a simulation model.

Based on our results, the virtual verification simulation model can enable the EtRL management system to operate at minimum risks.

### **Introduction**

Nowadays, environmental toxicology research is at the centre of interest, because environmental pollutions have a significant health burden on individuals and societies [1].

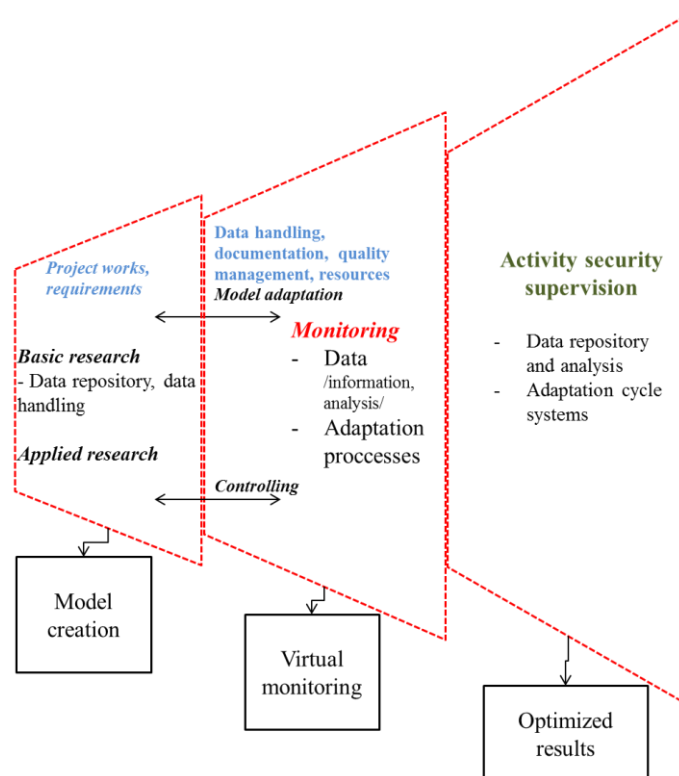
Environmental load agents that interfere with the endocrine system are called endocrine disruptor compounds (EDC). They have high health risks [2]. The results of the EDC effects confirmed by the DELPHI method, EDC exposure to the population of Europe can manifest in intellectual effects e.g. autism, loss of skills – dysfunctions and in hyperactivity. EDC also can cause serious medical costs, because of endometriosis, fibrosis, childhood obesity, adulthood diabetes (type II.), cryptorchidism, male infertility and diminution of the levels of testosterone. Their estimated cost within the EU, 1.28 % of total domestic products (approximately € 163 billion) annually.

The above mentioned supports, that it is important to develop a standardized methodology for the study of substances with EDC activity, as soon as possible. An important aspect of this is to make the results of basic and applied research of environment toxicology research laboratories can be directly utilized at the social (sectoral) level. All this, can be ensured by matching laboratory operations with international requirements (e.g. ISO), in this context the

structure of the data system is essential and it also means the controlled operation of the resources of the activity processes that can be traced and traced back. Systematic operation, therefore, represents the development of sustainable accuracy and result security. The material resource background and the methodical stability in the standardized laboratory operation create the possibility to utilize the research results directly in the society.

Since data-based, objective parameters controlled by a research laboratory operation, is the most efficient electronically, therefore, systematic control options with virtual verification have already been required.

In the present work the main goal is to solve this task pilot: with creation of simulation models, with definition the key elements and complex processes of environmental-toxicology laboratories and with persistent activity control.

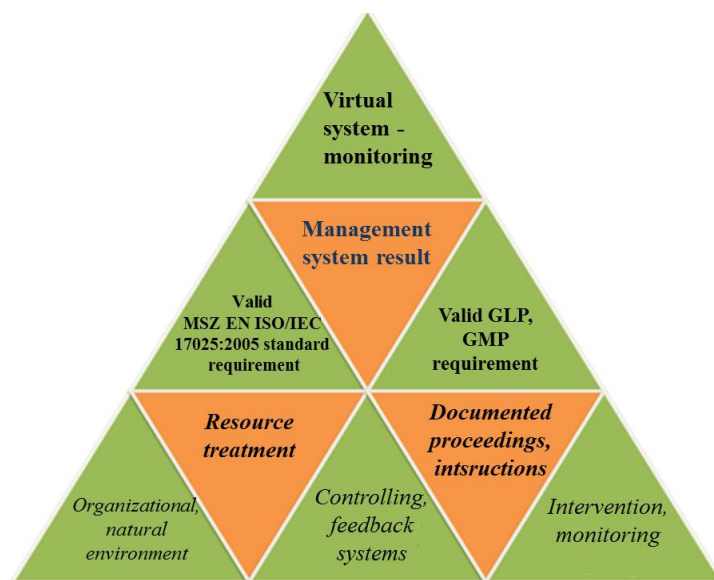


**Figure 1** Environment-toxicology research laboratory operating model with requirement compliance

### Research protocol

Firstly, in the research tasks, the selection of international requirements for the field of environmental toxicology (Et) research (theoretical / practical and organizational operation) was made resulting in the simultaneous adaptation of the specialized sciences, ISO, GLP and GMP requirements. In the next step, the activity target areas and the networks of resources implementing the activities have been set up. The next step was to create the target areas for action and the implementing activities of networks of resources. Then the identified system elements were defined depending on the requirements of the standard management. The junctions of the established network of connections were ranked according to graph attributes

(Figure 2) [3]. The responsibilities of human resources were assigned to the network connections, to which the appropriate powers were associated. According to this method, the personal requirements of the management system were defined. The management "pyramid" was therefore directed the methodological and resource elements of the project and research tasks, according to the criteria of the Et testing laboratory requirements. The standard requirements handle the safety of results of the environmental toxicology research laboratories (EtRL) with the safety indicators of the validated indicators of measurement and the safety of methodology; therefore they are handled by confidence intervals (Figure 3) [4,5]. Therefore virtual monitoring of the network connection system can be possible with the data from the activities of EtRL and with binary code (0, 1) of the system operation. Based on the method described above, the research and project systems of EtRL with safety code can also support independent controlling and auditing, which minimizes system certification risks (Figure 1).



**Figure 2** Environment-toxicology research laboratory hierarchical operation (according to grid-based relationships)

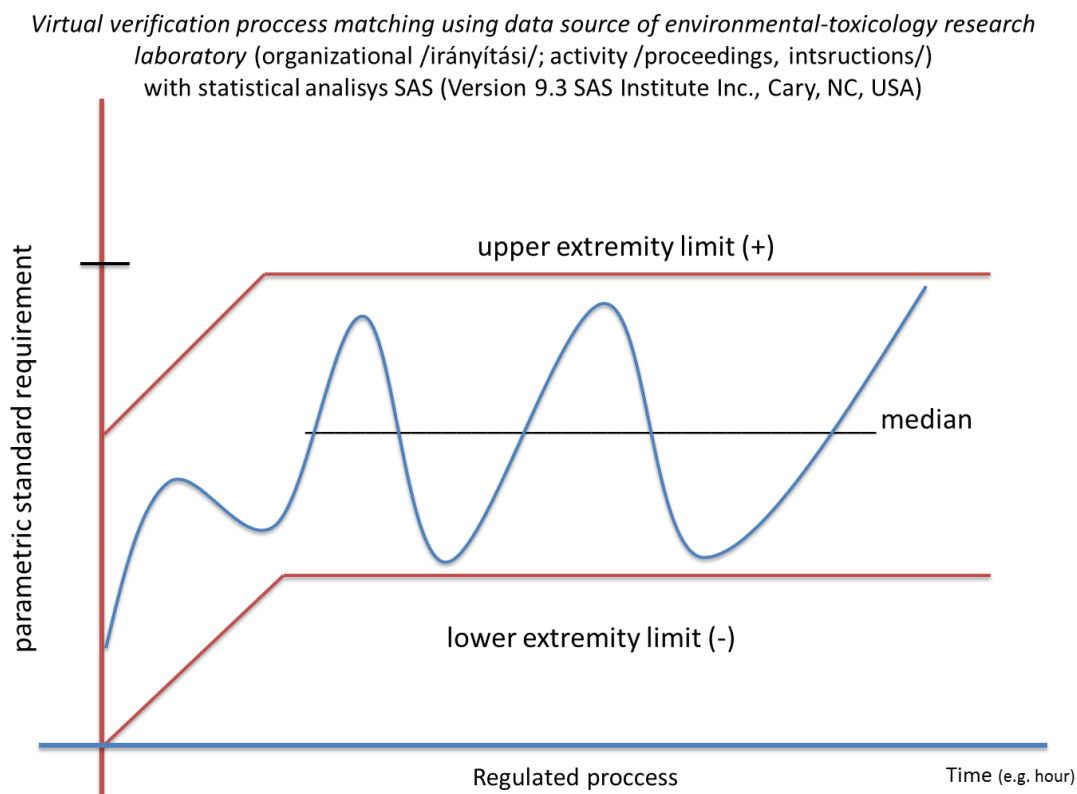
### Results, discussion

The system operation developed as described herein can be virtually monitored because the node structure outlined a hierarchical system operation, for which the management standard requirements were well suited.

The Et testing laboratory system operated according to the presented results, which is handled by confidence intervals can be interpreted as a “hyperspace”, which means the basis of virtual verification.

### Conclusion

With the help of this pilot simulation modelling, the EtRL operation management system has been designed so that international compliance can be followed by an external independent party using virtual verification.



**Figure 3** Validated system of Environment-toxicology research laboratory handled by confidence interval

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